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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,133	11/07/2005	Graeme Bilbe	BILBE1	7245
1444 7590 01/11/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER DUNSTON, JENNIFER ANN	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 01/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,133

Applicant(s)

BILBE ET AL.

Examiner

Jennifer Dunston

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 27-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 27-44 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 27-35, drawn to a method for screening a subject for or monitoring the progression of schizophrenia, bipolar disorder and/or ADHD, comprising detecting a level of expression of at least one gene selected from Table 1, Table 2 or Table 7 in a frontal pole tissue sample obtained from a subject.

Group II, claim(s) 36-38, drawn to a method for identifying agents for use in the treatment of schizophrenia, bipolar disorder, and ADHD, comprising contacting a sample of cells with a candidate agent, and detecting a level of expression of at least one gene.

Group III, claim(s) 39, drawn to a method of treating and preventing schizophrenia, bipolar disorder, and/or ADHD in a patient in need thereof, comprising administering the patient an effective amount of an agent that can increase or decrease the expression of at least one gene recited in the claim.

Group IV, claim(s) 40-42, drawn to a method of monitoring the efficacy of a treatment of a subject having schizophrenia, bipolar disorder, and/or ADHD, comprising comparing the level of expression of at least one gene selected from Tables 1 and 7 in a pre-administration sample and a post-administration sample.

Group V, claim(s) 43, drawn to a transgenic mouse whose genome comprises a disruption of any of the endogenous genes selected from Tables 1, 2 and 7.

Group VI, claim(s) 44, drawn to a method of making a rodent having schizophrenia, bipolar disorder, and/or ADHD, comprising subjecting the rodent to variable repeated stress during the last week of gestation and continuing until the natural delivery of a pup.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking Groups I-VI appears to be that they all relate to genes that are up or down regulated in tissues of stressed rats compared to non-stressed rats, which genes are disclosed in Tables 1, 2 and 7. However, the genes in Tables 1, 2 and 7 do not make a contribution over the prior art. For example, Hermfisse et al (Biochemical and Biophysical Research Communications, Vol. 225, pages 997-1005, 1996) teach the rat aldolase A gene of GenBank Accession No. U20643 (e.g., Figure 1), which is the first named gene of Table 1. Further, Hermfisse et al teach the detection of aldolase A expression by northern blot hybridization and S1 nuclease mapping (e.g., page 999). Therefore, the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

at least one gene selected from Tables 1, 2 and/or 7, as recited in claims 27 and 33 (Group I), at least one gene selected from Tables 1 and 2 or Table 7 (Group II), at least one gene selected from part A) or B) of claim 39 (Group III), at least one gene selected from Tables 1 and 7 or Table 2 (Group IV), and gene(s) selected from Tables 1, 2 and 7 (Group V).

Applicant is required, in reply to this action, to elect a single species (one combination of gene(s)) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claims 27 and 33 (Group I), claim 36 (Group II), claim 39 (Group III), claim 40 (Group IV), and claim 43 (Group V).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species relate to genes that are disclosed in Tables 1, 2 and 7. However, the genes in Tables 1, 2 and 7 do not make a contribution over the prior art. For example, Hermfisse et al (Biochemical and Biophysical Research Communications, Vol. 225, pages 997-1005, 1996) teach the rat aldolase A gene of GenBank Accession No. U20643 (e.g., Figure 1), which is the first named gene of Table 1. Further, Hermfisse et al teach the detection of aldolase A expression by northern blot hybridization and S1 nuclease mapping (e.g., page 999). Therefore, the technical feature linking the species does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston
Examiner
Art Unit 1636

/JD/

/Daniel M. Sullivan/
Primary Examiner
Art Unit 1636